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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,959	01/20/2004	Michael A. Martinelli		1480

7590 06/13/2005  
Donald E. Mahoney  
57 Eisenhower Circle  
Wellesley, MA 02482

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/760,959	Applicant(s) MARTINELLI, MICHAEL A.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 21 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because it lacks the organization for the apparatus as stated above and it contains terms not common in the art; i.e. synchronized chirp hyperthermia. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: on page 8, second paragraph, reference is made to a non-contact cooling using needles inserted into the tissue. The needles cannot be inserted without contacting the tissue.

Appropriate correction is required.

### ***Claim Objections***

Claim 23 is objected to because of the following informalities: a pulsing of the tissue temperature results from controlling the energy output. Pulsing the temperature is not a well defined step. Appropriate correction is required.

Claims 2-5, 16-19 and 21-22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are drawn to intended use that does not limit the apparatus structure.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

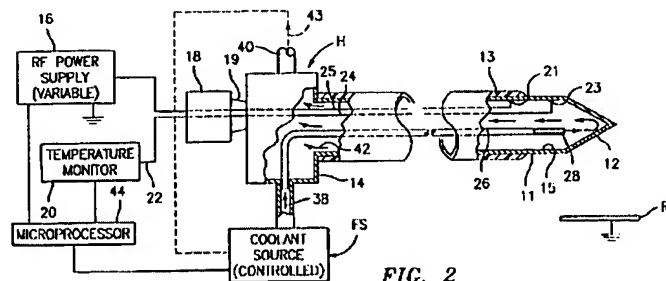
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 and 15-22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent 6,506,189 to Rittman et al.

Rittman et al. teach the delivery of RF energy to tissue via electrodes, the energy controlled by a microprocessor



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that includes temperature feedback (Fig. 2). Alternatives to RF energy are disclosed as microwave, laser, ultrasound, or other direct or alternating current power source (Col. 12, lines 14-18). A cooling means is disclosed, also controlled by the microprocessor (Fig. 2, # FS), that is clearly a temperature controlled fluid in thermal contact with the tissue. The microprocessor provides the means for controlling the energy to the tissue and has the capability to provide any temperature profile that is programmed into the microprocessor, including sequencing and waveform algorithms. The programming of temperature profiles is well known, not only in the medical arts, but also in arts such as heat treating metals.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,891,134 to Goble et al. Goble et al. teach a system and method for applying thermal energy to tissue, the method including introducing the distal end of the surgical device into a selected operation site; expanding the expandable device; filling the expandable device with a conductive saline solution; and applying output power to the bipolar electrode assembly to heat the conductive fluid. The method may include the further steps of monitoring the fluid temperature, and controlling the output power to the electrode assembly to maintain the temperature of the conductive fluid in a desired temperature range (Col. 2, lines 35-44). Controlling the output power will inherently result in temperature small fluctuations.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,506,189 to Rittman et al. in view of U.S. Patent 5,891,134 to Goble et al. Rittman et al. are discussed above and disclose that a variety of sizes and shapes of electrodes are known (Col. 1, lines 51-55), however, specific electrodes are missing. Goble et al., also discussed above, teach several configurations of electrodes. Planar electrodes are disclosed (Fig. 8, # 106) as are electrodes using shaped supports (Fig. 7, # 94 and Fig. 10). Electrodes on flexible or expandable structures are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the electrodes as taught by Goble et al. in the device of Rittman et al. to adapt to the tissue being treated.

### ***Conclusion***

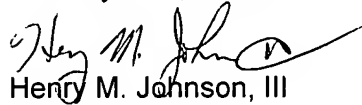
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,553,611 to Budd et al. teaches an inflatable spherical electrode. U.S. Patent 6,593,130 to Sen et al. teaches an inflatable cylindrical electrode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III  
Primary Examiner  
Art Unit 3739